UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

CVS PHARMACY, INC., RITE AID CORPORATION, AND RITE AID HDQTRS. CORP., Plaintiffs, vs. ABBVIE, INC., ABBOTT LABORATORIES, UNIMED PHARMACEUTICALS, LLC and BESINS HEALTHCARE, INC., Defendants.	Civil Action No. _____ JURY TRIAL DEMANDED

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs CVS Pharmacy, Inc., Rite Aid Corporation, and Rite Aid Hdqtrs. Corp. ("Plaintiffs") bring this civil action against Defendants AbbVie, Inc., Abbott Laboratories, Unimed Pharmaceuticals, LLC (collectively "AbbVie") and Besins Healthcare, Inc. ("Besins") under the antitrust laws of the United States. For their Complaint, Plaintiffs allege as follows:

I. INTRODUCTION

1. This is a civil antitrust action seeking treble damages and other relief arising out of Defendants' unlawful monopolization of a relevant market consisting of topical testosterone replacement therapies or transdermal testosterone replacement therapies ("TTRTs") through the filing and maintenance of sham patent litigation against putative generic competitors Teva Pharmaceuticals USA, Inc. ("Teva") and Perrigo Company ("Perrigo"). The filing and

maintenance of that sham litigation delayed Perrigo's launch of a lower-priced generic version of AndroGel 1%, AbbVie's blockbuster testosterone replacement product. But for AbbVie's sham patent litigation, Perrigo would have launched its generic version of AndroGel in June 2013 rather than on December 27, 2014, when Perrigo actually launched.

2. As a result of Defendants' unlawful monopolization, Plaintiffs and/or their assignors paid hundreds of millions of dollars more during the relevant time period to acquire branded AndroGel 1% formulation of testosterone than they would have paid to acquire Perrigo's generic version of the drug. Plaintiffs bring this action in order to recover those overcharges and for additional relief.

II. PARTIES

3. Plaintiff CVS Pharmacy, Inc. ("CVS") is a Rhode Island corporation with its principal place of business at One CVS Drive, Woonsocket, Rhode Island 02895. Plaintiff purchases substantial quantities of pharmaceutical products and other goods for resale to the public through more than 9,600 drugstores, approximately eleven mail service pharmacies, and twenty-seven specialty pharmacies owned and operated by its affiliates. Plaintiff brings this action on its own behalf and as the assignee of Cardinal Health, Inc. ("Cardinal") and McKesson Corporation ("McKesson"), national pharmaceutical wholesalers, which during the relevant period purchased AndroGel directly from Defendants for resale to CVS, and which have assigned their claims arising out of those purchases to CVS.

4. Plaintiffs Rite Aid Corporation and Rite Aid Hdqtrs. Corp. (collectively "Rite Aid") are corporations organized and existing under the laws of the State of Delaware with a principal place of business at 30 Hunter Lane, Camp Hill, Pennsylvania 17011. Rite Aid purchases substantial quantities of pharmaceutical products and other goods for resale to the public. Rite Aid brings this action on its own behalf and as the assignee of McKesson, which during the relevant

period purchased AndroGel directly from Defendants for resale to Rite Aid and which has assigned its claims arising out of those purchases to Rite Aid.

5. Defendant AbbVie, Inc. is a Delaware corporation having its principal place of business at One North Waukegan Road, North Chicago, Illinois 60064. AbbVie, Inc. develops, manufactures and markets prescription pharmaceutical products in the United States, including AndroGel.

6. Defendant Abbott Laboratories ("Abbott") is an Illinois corporation having its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064. Abbott develops, manufactures and markets a variety of healthcare and pharmaceutical products in the United States. On January 1, 2013, Abbott completed the spinoff of AbbVie, Inc., a corporation formed to hold Abbott's branded pharmaceutical business, including the marketing and sale of AndroGel. Prior to January 1, 2013, Abbott marketed AndroGel in the United States, either directly or through subsidiaries and affiliates.

7. Defendant Unimed Pharmaceuticals, LLC ("Unimed") is a wholly owned subsidiary of AbbVie with its principal place of business at 901 Sawyer Road, Marietta, Georgia 30062. Solvay Pharmaceuticals, Inc. ("Solvay") acquired Unimed in 1999, and Abbott acquired Solvay in 2010. Unimed developed and marketed AndroGel in the United States.

8. Defendant Besins Healthcare, Inc. n/k/a Ascend Therapeutics Inc. ("Besins") is a Delaware corporation with its principal place of business at 607 Herndon Parkway, Suite 210, Herndon, Virginia 20170. Besins manufactures AndroGel for AbbVie under a license agreement. Besins' employees, along with employees of Unimed, filed the patent application that led to issuance of U.S. Patent No. 6,503,894 ("the '894 patent").

9. All of Defendants' actions described in this Complaint were carried out by Defendants' various officers, agents, employees, or other representatives within the course and

scope of their duties and employment by Defendants, and/or with the actual, apparent, and/or ostensible authority of Defendants.

III. JURISDICTION AND VENUE

10. This action arises under section 2 of the Sherman Act, 15 U.S.C. § 2, and sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26, to recover treble damages, permanent injunctive relief, costs of suit and reasonable attorneys' fees for the actual and threatened injuries sustained by Plaintiffs resulting from Defendants' unlawful monopolization of the TTRT market. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1337(a).

11. Defendants transact business within this district and/or have an agent and/or can be found in this district. Venue is appropriate within this district under section 12 of the Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. §1391(b) and (c).

IV. REGULATORY BACKGROUND

12. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

13. When the FDA approves a brand manufacturer's NDA, the drug product is listed in an FDA publication titled Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book." The manufacturer may list in the Orange Book any patents that the manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. The manufacturer may subsequently list in the Orange Book within thirty

days of issuance any such patents issued after the FDA approves the NDA. 21 U.S.C. §§ 355(b)(1) & (c)(2).

14. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability, as it does not have the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

15. The Hatch-Waxman Amendments (also simply "Hatch-Waxman"), enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly New Drug Applications ("NDAs"). See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, as amended (1984). A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA, and must further show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug and is absorbed at the same rate and to the same extent as the brand drug—that is, that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug.

16. Bioequivalence exists when the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the active ingredient in its branded counterpart. 21 U.S.C. § 355(j)(8)(B).

17. Congress enacted the Hatch-Waxman Amendments to expedite the entry of legitimate (non-infringing) generic competitors, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

18. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historically high profit margins for brand manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generic drugs totaled $21.6 billion; by 2009 total prescription drug revenue had increased many-fold to $300 billion.

19. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");
ii. that the patent for the brand drug has expired (a "Paragraph II certification");
iii. that the patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or
iv. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

20. If a generic manufacturer files a Paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of: (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to market its product. This stay of FDA approval is sometimes referred to as the automatic "30-month stay."

21. The 30-month stay is triggered simply by the filing of a patent infringement action in response to a paragraph IV certification by the generic applicant, without regard to the merit or lack of merit of the lawsuit. Thus, brand manufacturers have a powerful economic incentive to file such actions even if they have no expectation of prevailing, because simply filing the action will delay generic competition by as much as 2 ½ years.

22. As an alternative to filing an ANDA, a generic applicant may file a special kind of NDA under 21 U.S.C. § 505(b)(2), which is a hybrid between an ANDA and a full NDA. A generic submitted for approval under section 505(b)(2) may differ slightly from the brand-name drug. See 21 C.F.R. § 314.54. The applicant may rely on the FDA's finding of safety and efficacy for a reference listed drug to the extent that the proposed product shares characteristics of the reference listed drug, but must submit additional data to the FDA demonstrating that any differences between the brand-name drug and the generic will not affect safety or efficacy.

23. Once the FDA approves a generic drug, the applicant may request from the FDA a therapeutic equivalence ("TE") rating. A TE rating is a code that reflects the FDA's determination whether a generic product is pharmaceutically and biologically equivalent to the reference-listed branded drug. Oral dosage products that are determined to be therapeutically equivalent to the reference-listed drug are assigned an "AB" rating. Generic products for which therapeutic equivalence cannot be determined are assigned a "B" or "BX" rating. An "AB" rating is extremely desirable for generic manufacturers. Generic substitution laws in all 50 states either permit or require pharmacists to dispense AB-rated generic drugs unless the physician has expressly directed the pharmacist to dispense the equivalent branded drug instead.

24. Generic versions of brand name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective, as their brand name counterparts. The only material difference between generic and brand name drugs is their price. The launch of a

generic drug thus usually brings huge cost savings for all drug purchasers. The Federal Trade Commission ("FTC") estimates that, by one year after market entry, the generic version takes over 90% of the brand's unit sales and sells for 15% of the price of the brand name product. In retail pharmacy chains, such as Plaintiffs, a generic typically achieves at least an 80% substitution rate within 90 days. As a result, brand name companies, such as AbbVie, view competition from generic drugs as a grave threat to their bottom lines.

25. Due to the price differentials between brand and generic drugs, and other institutional features of the pharmaceutical industry, including state generic substitution laws, pharmacists liberally and substantially substitute for the generic version when presented with a prescription for the brand-name counterpart. Since passage of the Hatch-Waxman Amendments, every state has adopted substitution laws that either require or permit pharmacies to substitute generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise by writing "dispense as written" or similar language on the prescription).

26. There is an incentive to choose the less expensive generic equivalent at every link in the prescription drug chain. Pharmaceutical wholesalers and retailers pay lower prices to purchase generic drugs than to purchase the corresponding brand-name drug. Health insurers and patients also benefit from the lower prices of generic products.

27. Until a generic version of the brand drug enters the market, there is no bioequivalent generic drug to substitute for, and to compete with, the branded drug, and therefore the brand manufacturer can continue to profitably charge very high prices (relative to cost) without losing sales. As a result, brand manufacturers, who are well aware of generics' rapid erosion of their brand sales, have a strong incentive to delay the introduction of generic competition into the market.

V. OPERATIVE FACTS

A. AndroGel

28. AndroGel is a brand-name transdermal testosterone gel product approved by the FDA for the treatment of hypogonadism, a clinical syndrome that results from failure of a man's body to produce adequate amounts of testosterone. It is estimated that this condition affects 2-6% of the adult male population in the United States. Hypogonadism is a lifelong condition that causes decreases in energy and libido, erectile dysfunction, and changes in body composition including decreased bone density. Patients with hypogonadism are typically treated with testosterone replacement therapy ("TRT"), in which exogenous testosterone is administered.

29. The first TRTs approved by the FDA were injectables consisting of testosterone dissolved in a liquid and then injected into a muscle of the body. Injectable testosterones were introduced in the 1950s and have been available in generic form for decades. They are administered every one to three weeks. While many patients receive injections at their doctors' office, some patients opt to self-administer injections at home or visit clinics specializing in TRT commonly known as "Low-T" centers. Because they are available in generic form, injectables generally require a five to ten dollar patient copay on most insurance plans and thus are the least expensive treatment method for hypogonadism.

30. Testosterone injections typically require two needles: a withdrawal needle and an injection needle. The withdrawal needle is typically a 20-gauge wide bore and 1-inch long needle required to withdraw the testosterone from the glass vial. After withdrawal, the needle must be switched to a 21- or 22-gauge narrow bore and 1.5-inch long needle to administer the injection. This needle must then be inserted deep into a muscle, typically the buttocks or thigh, until the needle is no longer visible. Because a deep intramuscular injection is required, this treatment method may cause pain and discomfort which will vary from patient to patient.

Injectables generally provide an initial peak in testosterone level at the time of injection followed by troughs or valleys as the injection wears off. This variation in testosterone level may cause swings in mood, libido, and energy.

31. TRTs may also be administered through a gel or patch applied to the skin and thereby absorbed into the bloodstream. This group of products is known as topical testosterone replacement therapies or transdermal testosterone replacement therapies ("TTRTs"). Androderm, the first testosterone patch, was released in the 1990s. It is applied once a day to the back, abdomen, thighs, or upper arms. The patch formulation delivers a steady level of testosterone without the peaks or valleys associated with injectables. It is relatively easy to apply, although the patch may cause skin irritation in some patients and may be visible depending on where it is applied. Testoderm, a testosterone patch worn on the scrotum, was also introduced in the 1990s.

32. AndroGel was launched in 2000 as the first FDA-approved testosterone gel. It is applied once a day to one or more application sites, including the upper arms, shoulders, and abdomen. AndroGel comes in two strengths: (1) 1%, which was the original formulation launched in June 2000; and (2) 1.62%, which was first sold in May 2011. At the time AndroGel 1% came on the market in 2000, it was available only in individual dose packets. In 2004, it became available in a metered-dose pump. AbbVie discontinued manufacture of the AndroGel 1% pump in December 2013.

33. AndroGel 1% was developed through a collaboration between Unimed and various subsidiaries of Besins' parent company. At the time of its launch, AndroGel 1% was marketed and distributed by Solvay, the parent company of Unimed. Abbott Laboratories acquired Solvay and Unimed in February 2010. At that time, Solvay was renamed Abbott Products Inc. In January 2013, Abbott completed the spinoff of AbbVie, a corporation formed to hold all of Abbott's proprietary pharmaceutical business, including AndroGel 1%.

34. As the first testosterone gel on the market, AndroGel achieved great commercial success and quickly became one of Solvay's "flagship" products. In 2009, AndroGel's U.S. net sales were approximately $604 million, and in 2010, that number grew to $726 million. After AbbVie acquired Solvay and Unimed in 2010, sales of AndroGel continued to grow, and AndroGel became one of AbbVie's blockbuster drugs. In 2011, U.S. net sales for AndroGel reached $874 billion, and, in 2012, U.S. net sales surpassed $1.15 billion. In 2013, AndroGel's U.S. net sales were approximately $1.035 billion, and in 2014, net sales totaled $934 million. After entry of generic versions of AndroGel 1%, AndroGel U.S. net sales fell to $694 million in 2015. Throughout this time, AbbVie maintained a high profit margin of approximately 65% on AndroGel.

35. Transdermal gels have several advantages over other forms of TRTs. A gel is relatively easy for a patient to apply without the potential for pain or discomfort associated with an injection. It also allows the patient to maintain a steady testosterone level without peaks and troughs. As compared to the patch form of testosterone, it has a lower rate of irritation and is not visible.

36. Gels such as AndroGel, however, are not without some drawbacks. There is a serious but rare risk of secondary exposure associated with gels. Such exposure may occur when testosterone is transferred from a patient to others, including women and children, through skin-to-skin contact. Precautions such as washing hands after application and covering the application site with a t-shirt can prevent such exposure. Gels may also cause skin irritation in some patients. Finally, some patients may dislike having to apply the gel daily.

37. After AndroGel was released in 2000, several other brand-name TTRTs were launched by competing pharmaceutical companies. Testim, a 1% gel available in a five gram tube, was approved in 2002. In 2011, two brand-name testosterone 2% gels were brought to

market: (1) Fortesta, a metered-dose pump product applied to the thighs; and (2) Axiron, a solution that is dispensed from a metered-dose pump and applied to the underarms using a silicon applicator. In 2014, Vogelxo, another brand-name low-volume testosterone gel, was launched along with an authorized generic version of the same product.

38. In addition to injectables and TTRTs, several other forms of TRTs have been approved by the FDA. Striant, a buccal testosterone tablet applied twice daily to the gums, was released in 2003. Testopel, a pellet that is surgically inserted in the hip, buttocks, or thigh every three to six months, was approved in 2008. And in 2014, the FDA approved Natesto, a nasal testosterone spray administered three times a day.

39. AndroGel 1% is protected by the '894 patent. That patent is owned by Besins and by Unimed, which as discussed above, was a wholly-owned subsidiary of Solvay until 2010. Laboratoires Besins Iscovesco SA, a subsidiary ultimately owned by Besins' parent company and now known as Laboratoires Besins Iscovesco SAS ("LBI SAS"), licensed to Unimed certain intellectual property rights to AndroGel. In return, Unimed was obligated to pay a royalty on net sales of AndroGel. Under a separate supply agreement, LBI SAS agreed to manufacture and to sell to Unimed AndroGel products for sale and distribution by Unimed in the United States.[1]

A. The '894 Patent Litigation

40. The initial patent application that resulted in the '894 patent claimed a pharmaceutical composition of a testosterone gel including a penetration enhancer, which according to the patent application "is an agent known to accelerate the delivery of the drug through the skin into the bloodstream." The patent application claimed all penetration enhancers

[1] AbbVie and Besins later amended the license and supply agreements to include AndroGel 1.62%. Royalties on U.S. sales of AndroGel 1.62% are paid to LBI SAS or Besins Healthcare Luxembourg SARL ("BHL SARL").

including isopropyl myristate, the penetration enhancer actually used in AndroGel. The patent examiner at the U.S. Patent and Trademark Office ("PTO") rejected the claim to all penetration enhancers. Thereafter, Unimed and Besins submitted an amendment narrowing their claim so as to name only twenty-four specific penetration enhancers, including isopropyl myristate. Id. at *2-3. After a series of additional amendments, Unimed and Besins further narrowed their claim to a single penetration enhancer, isopropyl myristate. On this basis, the '894 patent was issued on January 7, 2003. It is scheduled to expire on January 6, 2020.

41. As is often the case with successful pharmaceutical products, generic manufacturers sought to enter the market to compete with AndroGel. In December 2008, Perrigo submitted two ANDAs to the FDA for a generic testosterone 1% gel in both pump and packet form. The ANDAs referenced AndroGel and the '894 patent. However, the Perrigo product contained isostearic acid as its penetration enhancer rather than AndroGel's isopropyl myristate, the sole enhancer claimed in the '894 patent.

42. Pursuant to the procedures established by the Hatch-Waxman Act, Perrigo in June 2009 served paragraph IV notices on both Unimed and Besins as co-owners of the '894 patent. In those notices, Perrigo disclosed the filing of its ANDAs for a generic 1% testosterone gel. Perrigo further asserted that its ANDAs would not infringe the '894 patent for AndroGel because the Perrigo products did not contain "about 0.1% to about 5% isopropyl myristate," the sole penetration enhancer formulation claimed in the patent. Perrigo also stated in its notices that the prosecution history of the '894 patent would estop Unimed and Besins from filing a patent infringement claim. Finally, Perrigo offered to provide to outside counsel representing Unimed and Besins confidential access to its full ANDAs for generic AndroGel.

43. Thereafter Unimed and Besins, along with Unimed's parent Solvay, jointly retained the law firm of Finnegan, Henderson, Farabow, Garrett & Dunner, LLP ("Finnegan,

Henderson") to assess the Perrigo paragraph IV notices and the Perrigo ANDAs. Finnegan, Henderson obtained confidential access to the full ANDAs and confirmed that Perrigo's ANDAs specified isostearic acid as a penetration enhancer, not isopropyl myristate. Besins also separately retained the law firm of Foley & Lardner LLP ("Foley & Lardner"). Outside counsel at Foley & Lardner did not receive confidential access to the ANDAs.

44. On July 17, 2009, Solvay and Unimed issued a press release announcing that "[a]fter careful evaluation" the companies had decided not to file a patent infringement suit against Perrigo. The press release explained that the Perrigo product "contains a different formulation than the formulation protected by the AndroGel patent." It further stated that "[t]his distinction played a role in the company's decision not to file patent infringement litigation at this time," but "the company does not waive its right to initiate patent infringement litigation at a later stage based on new or additional facts and circumstances." The ultimate decision not to file suit was made by Solvay in-house attorneys Shannon Klinger, Peter Edwards, and Dominique Dussard. Besins also determined that it was "standing down" from bringing an infringement suit but did not join in the Solvay press release or issue its own public announcement.

45. Sometime in 2009, the FDA became aware of cases of accidental secondary exposure of children to TTRTs due to skin-to-skin transference from patients using these products. Based on this information, the FDA required safety-related labeling changes and a Risk Evaluation and Mitigation Strategy ("REMS") for transdermal testosterone gel products currently on the market. Thereafter, Auxilium Pharmaceuticals, Inc., the manufacturer of Testim, submitted a citizen petition to the FDA regarding a generic version of Testim. To facilitate the drug approval process, the FDA permits private entities to provide comments and opinions by filing citizen petitions. 21 C.F.R. § 10.30. A petition can request that the FDA "issue, amend, or

revoke a regulation or order or take or refrain from taking any other form of administrative action." Id.

46. On August 26, 2009, in response to the Auxilium citizen petition, the FDA directed that any application for a generic testosterone gel product containing a penetration enhancer different from the penetration enhancer in the referenced brand-name drug would be required to be submitted as a section 505(b)(2) NDA rather than an ANDA. The FDA also required the application to include certain additional safety studies regarding the risk of secondary exposure.

47. On April 9, 2010, AbbVie, now the owner of AndroGel, filed its own citizen petition with the FDA seeking assurance that Perrigo would be required to resubmit its 2009 ANDAs for generic AndroGel as section 505(b)(2) NDAs. In that petition, AbbVie noted the FDA's ruling in response to the Auxilium citizen petition regarding all generic testosterone products containing penetration enhancers different from those contained in the reference-listed brand-name drug. AbbVie also requested that Perrigo be directed to provide to the AndroGel patent holders a new paragraph IV notice. Finally, it asked that Perrigo be required to conduct transfer and hand-washing studies as set forth in the FDA's response to the Auxilium petition.

48. On October 4, 2010, the FDA granted in part and denied in part AbbVie's citizen petition. The FDA directed that any application by a generic manufacturer for a product referencing AndroGel containing a different penetration enhancer be submitted as a section 505(b)(2) NDA. The FDA also agreed that the applicants would be required to submit new paragraph IV notices.

49. On January 13, 2011, Teva filed a section 505(b)(2) NDA for its generic version of AndroGel 1% which described a different penetration enhancer, isopropyl palmitate, from the enhancer AbbVie used in its brand-name AndroGel. The application sought approval to

manufacture and to distribute the product in two different packet sizes as well as in a pump form. This application superseded an ANDA for generic testosterone that Teva had filed on December 29, 2008, prior to the FDA's ruling on the Auxilium citizen petition.

50. On March 16, 2011, Teva sent to Solvay, AbbVie, Unimed, and Besins a paragraph IV notice regarding its section 505(b)(2) NDA. Teva asserted that its product did not infringe the '894 patent because "the Teva formulation does not contain isopropyl myristate," the only penetration enhancer claimed in the '894 patent. Teva laid out the prosecution history of the '894 patent and its position that, because the claims of the '894 patent were narrowed to disclose only isopropyl myristate, "the prosecution history estops the patentees from asserting infringement under the doctrine of equivalents." Teva also offered confidential access to certain information regarding its section 505(b)(2) NDA to allow the patent holders to assess whether an infringement action would have merit.

51. AbbVie retained outside counsel at the law firm of Munger, Tolles & Olson LLP ("Munger Tolles") to evaluate the Teva paragraph IV notice. Counsel at Munger Tolles was provided with access to the Teva section 505(b)(2) NDA and provided in-house counsel at AbbVie with its opinion. Besins again retained Foley & Lardner to evaluate the notice. Foley & Lardner had confidential access to the NDA and submitted its analysis to Besins.

52. On April 29, 2011, within 45 days after receiving the paragraph IV notice, AbbVie, Unimed, and Besins commenced an action in the U.S. District Court for the District of Delaware alleging that Teva's product infringed the '894 patent. See Abbott Prods., Inc. v. Teva Pharm. USA, Inc., No. 11-384 (D. Del. Apr. 29, 2011). The suit against Teva triggered the Hatch-Waxman automatic stay of FDA approval of the Teva product. Consequently, the FDA could not approve Teva's generic testosterone drug for 30 months after March 16, 2011 or until September 17, 2013, unless the district court resolved the lawsuit sooner.

53. The intellectual property ("IP") litigation group at AbbVie had direct accountability for patent litigation. Four in-house patent attorneys in that group had final responsibility for evaluating the Teva paragraph IV notice and made the decision to file the patent infringement suit against Teva: (1) Johanna Corbin; (2) Adam Chiss; (3) Anat Hakim; and (4) Jose Rivera. All of these attorneys had extensive experience in patent law and with AbbVie. Corbin has worked in the AbbVie IP group since 2005 and is currently its vice president and the lead IP attorney. Chiss was divisional vice president of IP litigation and before that had served as senior counsel in IP litigation. Anat Hakim was divisional vice president and associate general counsel of IP litigation at AbbVie and previously had been a partner at Foley & Lardner. Finally, Rivera was a divisional vice president of the IP group and had previously worked in private practice. The general counsel of AbbVie, Laura Schumacher, also signed off on the final decision. Schumacher has been with AbbVie since 2005. No business persons at AbbVie were involved in the decision to sue. At trial, AbbVie presented evidence that the decision whether to file a complaint is always made solely by the legal department and does not require approval from management.

54. As for Besins, the decision to sue was made by Thomas MacAllister, its in-house counsel. MacAllister is an experienced intellectual property attorney who previously worked as a patent examiner at the U.S. Patent and Trademark Office. Besins conferred with outside counsel as well as AbbVie about the Teva product and potential litigation. Like AbbVie, Besins or its agents had confidential access to the portions of Teva's NDA that disclosed the formulation of its product prior to filing the complaint against Teva. In addition, in-house counsel for Besins conferred with in-house counsel for AbbVie before making the decision to initiate the lawsuit.

55. Around this time, AbbVie also was preparing for FDA approval and launch of its low-volume formulation of AndroGel, known as AndroGel 1.62%. The FDA issued final

approval of brand-name AndroGel 1.62% on April 29, 2011, and AbbVie began selling it in May 2011. The 1.62% formulation is indicated for the same condition and has the same active ingredient as the original formulation of AndroGel, but allows patients to get the same therapeutic effect using less total gel. Sales of AndroGel 1.62% grew more slowly after launch in 2011 than Defendants initially anticipated, but by June 2012, AndroGel 1.62% constituted the majority of total AndroGel sales. AndroGel 1.62% accounted for total AndroGel sales as follows: 57% during the last 7 months of 2012, 67% in 2013, 76% in 2014, and 83% in 2015.

56. In June 2011, Teva submitted a case status report proposing a schedule for early summary judgment proceedings in the patent infringement suit in the District of Delaware. AbbVie, Unimed, and Besins filed a supplemental case status report opposing any summary judgment proceedings. On August 1, 2011, before discovery had commenced, Teva filed a motion for summary judgment. Teva asserted that based on prosecution history estoppel there could be no viable claim of infringement of the '894 patent. On October 25, 2011, the court set trial on the issue of prosecution history estoppel for May 21, 2012.

57. On August 18, 2011, AbbVie filed a citizen petition with the FDA requesting that it refrain from granting a therapeutic equivalence rating to section 505(b)(2) products referencing AndroGel, including Teva's testosterone product, or in the alternative, requesting that it assign the product a BX rating. If a BX rating were assigned, there could be no automatic substitution at the pharmacy under state generic substitution laws.

58. Meanwhile, on July 4, 2011, Perrigo re-filed its application for generic testosterone 1% gel as a section 505(b)(2) NDA. On September 20, 2011, Perrigo sent AbbVie, Unimed, and Besins a new paragraph IV notice. As in its 2009 notice, Perrigo certified that the '894 patent was not infringed because its generic testosterone product did not contain "about 0.1% to 0.5% isopropyl myristate," the penetration enhancer claimed in the patent.

59. Perrigo's letter also explained that the prosecution history of the '894 patent precluded any valid infringement claim. Perrigo stated that "a lawsuit asserting the '894 patent against Perrigo would be objectively baseless and a sham, brought in bad faith for the improper purpose of, inter alia, delaying Perrigo's NDA approval." It further asserted that "a bad faith motive for bringing such a suit would be particularly apparent in light of representations and admissions made, inter alia, in [Solvay's] Friday, July 17, 2009 press release." Perrigo offered confidential access to certain information regarding its NDA. Again, AbbVie and Unimed retained Munger Tolles as outside counsel to analyze whether Perrigo's proposed product infringed the '894 patent. Foley & Lardner evaluated Perrigo's NDA on behalf of Besins and also issued its opinion to Besins.

60. On October 31, 2011, AbbVie, Unimed, and Besins filed suit in the District of New Jersey alleging that Perrigo's 1% testosterone gel infringed the '894 patent. See Abbott Prods., Inc. v. Perrigo Co., 11-6357 (D.N.J. Oct. 31, 2011). As in the Teva litigation, the filing of the complaint against Perrigo triggered an automatic 30-month stay under the Hatch-Waxman Act. Thus, absent a court ruling or settlement resolving the litigation, the stay would preclude final FDA approval of the Perrigo generic testosterone product until March 20, 2014.

61. The same four AbbVie in-house attorneys as had made the decision to sue Teva again made the decision to file the suit against Perrigo with approval from the same general counsel. They conferred with outside counsel, who had confidential access to the Perrigo section 505(b)(2) NDA. No AbbVie business person was involved in the decision to file the Perrigo action. After consultation with AbbVie and outside counsel, Besins' same in-house attorney made the decision that it would join in bringing the Perrigo litigation.

62. AbbVie reached out to Teva to discuss an amicable resolution of the dispute before AbbVie filed its complaint in April 2011. Perry Siatis, an in-house attorney for AbbVie,

was AbbVie's main negotiator. At that time, Siatis was Divisional Vice President of the IP strategy group and head intellectual property attorney at AbbVie. Although that initial contact did not lead to a settlement, AbbVie again raised the subject with Teva during an in-person meeting on October 28, 2011, three days after the court in the Teva litigation had set a trial date. On December 20, 2011, the parties reached a final settlement in the Teva litigation, in which Teva received a license to launch its generic AndroGel product beginning December 27, 2014.

63. While the Teva negotiations were ongoing, settlement negotiations were taking place in the Perrigo litigation. Sometime on or before November 3, 2011, Siatis approached Perrigo to initiate settlement negotiations. On December 8, 2011, the parties executed a binding term sheet, which included the dismissal of all claims and counterclaims with prejudice. In addition, AbbVie agreed to pay Perrigo $2 million dollars as reasonable litigation expenses.

64. During the negotiations Perrigo pushed for an earlier entry date but ultimately accepted an entry date of January 1, 2015. However, the settlement contained an acceleration clause whereby Perrigo would be permitted to launch earlier if another generic came to market. As a result of the Teva settlement, Perrigo's licensed entry date was moved up to December 27, 2014 under the acceleration clause.

65. On February 14, 2012, the FDA approved Teva's section 505(b)(2) NDA for the packet presentation of its TTRT product. During review of the application, the FDA identified a potential safety concern with the packaging used in the pump presentation of the drug. In response to this concern, Teva withdrew the pump presentation from its application. As a result, the FDA approved Teva's product in packet form only.

66. After receiving FDA approval, Teva waited for the FDA Office of Generic Drugs to assign a TE rating for its product. On December 21, 2012, AbbVie filed a citizen petition

supplement requesting that the FDA refrain from granting a TE rating to Teva's product or, in the alternative, grant Teva's product a BX rating.

67. Later, on January 31, 2013, the FDA approved Perrigo's section 505(b)(2) NDA for its generic version of AndroGel 1%. Thereafter, the FDA considered a TE rating for Perrigo's generic product. During this period, AbbVie filed an additional citizen petition on December 11, 2013. The December 11, 2013 citizen petition supplemented the August 18, 2011 citizen petition and requested that the FDA issue a BX rating for Perrigo's product.

68. In the months leading up to its December 27, 2014 licensed entry date, Perrigo took a number of steps to follow up with the FDA regarding its TE rating. Perrigo sent three letters to the FDA. It received no response other than being informed that the FDA needed more time to evaluate the therapeutic equivalence of the product.

69. Perrigo filed a lawsuit against the FDA in the United States District Court for the District of Columbia on March 21, 2014. See Perrigo Israel Pharm. Ltd. v. U.S. Food & Drug Admin., No. 14-475 (D.D.C. Mar. 21, 2014). Perrigo asserted that the FDA had engaged in unreasonable delay. It requested that the court enter a mandatory injunction compelling the FDA to publish a TE rating for Perrigo's NDA product as soon as possible. On April 10, 2014, the FDA filed its first response to the lawsuit. The FDA contended that "Perrigo has itself obviated the need for a prompt decision by reaching an agreement with the innovator not to market until December 2014." The FDA further represented that it expected to issue a TE rating for Perrigo's product "by July 31, 2014—some five months before Perrigo's planned product launch."

70. On July 23, 2014, the FDA determined that Perrigo's section 505(b)(2) NDA product was therapeutically equivalent to AndroGel and issued it an AB rating.2 That same day,

[2] Perrigo voluntarily dismissed the lawsuit on July 24, 2014, one day after the FDA issued its TE rating to Perrigo.

however, the FDA assigned a BX rating to Teva's product. Specifically, the FDA concluded that the data submitted by Teva was "insufficient to determine TE [therapeutic equivalence] to AndroGel 1%." As a result, under all state laws, the Perrigo generic testosterone product would be auto-substitutable at the pharmacy for brand-name AndroGel 1% prescriptions, but the Teva product would not.

71. Perrigo launched its AB-rated generic version of AndroGel 1% on December 27, 2014, its licensed entry date under the settlement agreement with defendants. Perrigo achieved its goal to obtain an AB rating for its product and would have challenged the FDA had it received only a BX rating.

72. But for Defendants' patent litigation against Perrigo and the resulting 30-month stay and eventual settlement, Perrigo would have received its AB rating in June 2013 rather than July 2014 and would have launched its AB-rated product at that time. Plaintiffs and other purchasers would have received the benefits of a lower-priced generic AndroGel 1% product in June 2013 rather than December 27, 2014.

A. Objective and Subjective Baselessness

73. The patent litigation brought against both Teva and Perrigo was objectively baseless. As noted above, neither the Teva product nor the Perrigo product contained the penetration enhancer isopropyl myristate, the only penetration enhancer claimed in the '894 patent. Instead of isopropyl myristate, Teva used isopropyl palmitate and Perrigo used isostearic acid. Unimed and Besins obtained the '894 patent only by narrowing the initial broad claim in their patent application covering all penetration enhancers to a very limited claim covering only a single penetration enhancer, isopropyl myristate, at a particular concentration.

74. The purpose of prosecution history estoppel is to protect competitors of the patentee from liability for patent infringement under the doctrine of equivalents if the

prosecution history shows that a potential equivalent not specifically disclosed in the patent has been purposely and not tangentially excluded from the scope of the patent. That is exactly what occurred here. AbbVie and Besins purposely excluded all penetration enhancers other than isopropyl myristate during prosecution in order to convince the patent examiner to issue the patent. AbbVie and Besins could not purposely surrender claims to all penetration enhancers except one in order to obtain the patent in the first instance and then claim infringement when a competitor used an enhancer that they had deliberately surrendered. No reasonable litigant in Defendants' position could have realistically expected to prevail on the merits of their patent infringement claims against Teva and Perrigo.

75. The patent litigation against Teva and Perrigo was also subjectively baseless. Defendants AbbVie and Besins had actual knowledge that the patent infringement suits were baseless and destined to fail. They filed those suits only for the purpose of delaying Teva's and Perrigo's entry into the market as competitors, not with any expectation of actually winning either case.

76. As noted above, Solvay issued a press release in 2009 announcing the company's decision not to sue Perrigo for infringement of the '894 patent because the Perrigo product "contain[ed] a different formulation than the formulation protected by the AndroGel patent." Besins also decided to "stand down" from pursuing an infringement case. The facts supporting both companies' decision not to pursue Perrigo for infringement did not change between 2009 and 2011, when the companies changed their minds and filed suit.

77. The individuals who made the decision on AbbVie's behalf to file objectively baseless lawsuits against Teva and Perrigo were four highly experienced patent attorneys who had sign-off from AbbVie's general counsel. Besins' decision to sue was likewise made by an experienced patent attorney. No business people were involved in either decision. The decision-

makers at both companies were aware of the paragraph IV notices sent by Teva and Perrigo, which identified the penetration enhancers used by Teva and Perrigo and made it clear that those products did not contain the single penetration enhancer claimed in the '894 patent. Outside counsel for AbbVie and Besins had access to the section 505(b)(2) NDAs and were able to confirm the representations made in the paragraph IV notices. The paragraph IV notices also described the doctrine of prosecution history estoppel and the Perrigo notice explicitly asserted that any infringement suit against it would be a sham.

78. As experienced patent attorneys, the decision-makers at both companies were subjectively aware that neither the Perrigo product nor the Teva product literally infringed the '894 patent, that the only possible means of proving infringement was the doctrine of equivalents, and that AbbVie and Besins could not possibly invoke the doctrine of equivalents in light of the prosecution history of the patent. These experienced patent attorneys could not possibly have overlooked the objective baselessness of the litigation. The baselessness of the litigation, in combination with the experience of the decision-makers and the facts known to them, are strong circumstantial evidence of their subjective intent.

79. The decision-makers at AbbVie and Besins were also aware that AndroGel was a blockbuster product, bringing in hundreds of millions of dollars in sales every year at very high profit margins. They were aware that the entry of generic versions of AndroGel would significantly erode these blockbuster profits. Their decision to file objectively baseless lawsuits against their would-be generic competitors was based on a desire to staunch, at least for a time, this imminent financial reversal. These decision-makers had no expectation of prevailing in either case, but, under the regulatory scheme, merely filing the lawsuits was sufficient to delay generic entry and thereby achieve the desired outcome.

VI. MARKET POWER AND MARKET DEFINITION

80. By filing sham litigation and delaying generic entry, Defendants were able to maintain monopoly power in a relevant market consisting of the sale of TTRTs in the United States.3

81. Transdermal testosterone replacement therapies, or topical testosterone replacement therapies, are a relevant antitrust product market based on both reasonable interchangeability and cross-elasticity of demand. There is little cross-elasticity of demand between TTRTs and other testosterone replacement therapies, such as injectables. Injectables have been on the market for many years and are available at a fraction of the cost of AndroGel and other TTRTs, yet have not taken significant sales away from TTRTs. AbbVie has been able to raise the price of AndroGel consistently and repeatedly while still increasing its sales.

82. Within the TTRT market, AndroGel enjoyed a 71.5% market share at the time the first sham lawsuit against Teva was filed in April 2011, and a share of 63.6% at the time the sham lawsuit against Perrigo was filed in October 2011. AndroGel's market share remained above 60% until the end of 2014, when Perrigo launched the first generic version of AndroGel 1%. AbbVie was able to maintain a profit margin of more than 65% during the relevant time period, even after accounting for rebates. These market shares and margin figures are sufficient to establish monopoly power.

83. Defendants' monopoly power is further supported by the existence of significant barriers to entry. Any prospective entrant into the TTRT market must invest large amounts of time and capital in research and development. In addition, there are significant technical and

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[3] Plaintiffs believe and have alleged in other litigation that there is a narrower relevant product market consisting of sales of AndroGel 1% and its AB-rated generic equivalents. However, this Court has already determined that, even in the broader market of TTRTs, AbbVie and Besins have monopoly power. *See* paragraph 91 *infra*.

regulatory requirements in the pharmaceutical business that do not exist with respect to ordinary consumer products. Branded drugs must be approved by the FDA through the submission of an NDA, and approval of an NDA is a lengthy and expensive process.

84. Even after a branded drug is approved, brand-name drug companies face significant barriers in attempting to convince physicians to prescribe the product, which typically involves the use of a trained and knowledgeable sales force. The marketing of prescription drugs is itself highly regulated. See generally 21 U.S.C. § 331. Sales representatives are not permitted to claim that their company's product is better or more effective than a competitor's product, and are not permitted to promote the drug for uses other than those approved by the FDA. The Hatch-Waxman regulatory scheme itself creates barriers to entry in the form of the automatic 30-month stay and other regulatory exclusivities, which are designed as incentives to branded and generic manufacturers to invest time and effort in bringing drugs to market.

85. The relevant geographic market is the United States.

VII. INTERSTATE COMMERCE

86. The drugs at issue in this case are sold in interstate commerce. Defendants' unlawful activities, as alleged above, have occurred in, and have had a substantial impact on, interstate commerce.

VIII. EFFECT ON COMPETITION AND INJURY TO PLAINTIFFS

87. Defendants' objectively and subjectively baseless patent litigation against Perrigo and Teva had the purpose and effect of delaying the entry of generic versions of AndroGel 1% and protecting branded AndroGel from generic competition. As a result of that conduct, purchasers of the drug have been deprived of the benefits of the free and open competition that the antitrust laws are intended to foster.

88. But for Defendants' unlawful monopolization, Perrigo would have launched an AB-rated generic version of AndroGel 1% in June 2013 rather than on December 27, 2014, when Perrigo actually launched. During the period from June 2013 through August 2017, Defendants unlawfully obtained $448 million in profits that they would not otherwise have obtained if Perrigo had launched its generic AndroGel 1% product in June 2013. Those ill-gotten gains were obtained at the expense of purchasers of branded AndroGel 1% and AndroGel 1.62%, who would otherwise have purchased Perrigo's less expensive generic AndroGel 1%.

89. But for Defendants' unlawful monopolization, beginning in June 2013, Plaintiffs or their assignors would have purchased the lower-priced Perrigo generic in place of the higher-priced branded AndroGel for a significant portion of their requirements of the drug. The difference between what Plaintiffs (or their assignors) actually paid to acquire AndroGel and what they would have paid but for Defendants' antitrust violation constitute overcharges. These overcharges are injury of the type the antitrust laws were designed to prevent and flow from that which makes Defendants' acts unlawful.

90. Plaintiffs have purchased and continue to purchase substantial amounts of AndroGel. As a direct result of the illegal conduct alleged herein, Plaintiffs and their assignors have paid prices for that drug that are substantially greater than the prices they would have paid absent the illegal conduct alleged herein.

IX. PRIOR LITIGATION

91. The facts alleged in paragraphs 28 through 86 above have been found and adjudicated by this Court in prior litigation entitled Federal Trade Comm'n v. AbbVie, Inc. et al., Civil Action No. 14-5151 (E.D. Pa. June 29, 2018) (the "FTC case"). See Doc. No. 439 (Findings of Fact and Conclusions of Law). Each Defendant herein was a defendant in the FTC case and had a full and fair opportunity to litigate those facts, including a three-week nonjury

trial before Judge Harvey Bartle III of this Court. Accordingly, each Defendant is collaterally estopped to relitigate those facts.

92. The filing of the FTC case has tolled the statute of limitations applicable to Plaintiffs' claims from the date the case was filed (September 8, 2014) until today.

X. CLAIM FOR RELIEF

VIOLATION OF 15 U.S.C. § 2 MONOPOLIZATION

93. Plaintiffs incorporate by reference the allegations in paragraphs 1 through 92 above as though fully set forth herein.

94. At all relevant times, Defendants possessed monopoly power in the relevant market.

95. Through their sham litigation against Perrigo and Teva, as set forth above, Defendants have willfully maintained their monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by competing on the merits.

96. Defendants' conduct has substantially harmed competition in the relevant market.

97. There is and was no cognizable procompetitive justification for Defendants' actions.

98. As a direct and proximate result of Defendants' monopolization, as alleged herein, Plaintiffs have suffered injury to their business and property in the form of overcharges.

XI. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs pray for judgment against Defendants and for the following relief:

A. A declaration that the conduct alleged herein is in violation of Section 2 of the Sherman Act;

B. A permanent injunction enjoining Defendants from engaging in similar conduct in the future, and requiring them to take affirmative steps to dissipate any continuing anticompetitive effects of their conduct;

C. An award of Plaintiffs' overcharge damages, in an amount to be determined at trial, trebled;

A. An award of Plaintiffs' costs of suit, including reasonable attorneys' fees as provided by law; and

B. Such other and further relief as the Court deems just and proper.

XII. JURY DEMAND

Plaintiffs demand a trial by jury of all issues so triable.

Dated: August 17, 2018

Respectfully submitted,

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